UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,349	03/16/2001	Wolfgang Rohde	07258-022001	4891

7590 09/05/2002

Pillsbury Winthrop
Ninth Floor East Tower
1100 New York Avenue NW
Washington, DC 20005-3918

EXAMINER	
KUBELIK, ANNE R	
ART UNIT	PAPER NUMBER
1638	9

DATE MAILED: 09/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,349	ROHDE ET AL.	
	Examiner	Art Unit	
	Anne Kublik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/0/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. As requested in Paper No. 5, the preliminary amendment filed 25 June, 2001, claims 1-9 have been cancelled, claims 10-12 and 16-18 have been amended and claims 19-27 have been added. Claims 10-27 are pending.

2. With respect to the amendments filed 9 July, 2002, the amendments to claim 16 were entered. However, the amendments to the specification were not entered, because no marked-up copy of the paragraphs was submitted, as dictated by revised 37 CFR 1.121. Applicant should amend the specification by presenting individual replacement paragraphs, together with instructions as to the paragraph to be replaced, as well as a marked-up copy of the paragraph showing the changes.

Sequence Rules

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from the specification on pg 8, line 15, pg 9, line 15, and pg 10, 3rd line from the bottom,

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Specification

4. The disclosure is objected to because of the following informalities:

a. On pg 1 and 4, there are footnotes indicating translator's notes. Clarification and correction of this is required.

b. The specification is missing section headings (*e.g.*, Background of the Invention and Brief Description of the Drawings). Additionally, the description of the drawings should be located after the Summary of the Invention and before the Detailed Description of the Invention. See 37 CFR 1.77(b).

c. The letter quality is so poor that many words are difficult to read. Thus, a substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a).

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed and 3) a request for entry of the substitute specification.

Drawings

5. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the

application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 10-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing potato plants that are tolerant of drought, fungal infection and salt by transformation with a nucleic acid encoding the pr17 protein operably linked to an N-terminal extension of SEQ ID NO:1, does not reasonably provide enablement for a method of producing plants that are tolerant of temperature extremes by transformation with that nucleic acid or other derivatives of pr17 or a method of using a multitude of DNA molecules that encode a protein with "an intrinsic affinity to plasmodesmata" to produce any and all plant species that are tolerant of drought, fungal infection, salt and temperature. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method of using a multitude of DNA molecules that encode a protein with "an intrinsic affinity to plasmodesmata" to produce plants that are tolerant of drought, fungal infection, salt and temperature.

The instant specification, however, only provides guidance for production of a vector encoding the pr17 protein operably linked to an N-terminal extension of SEQ ID NO:1 (example

1); transformation of the vector into potato (example 2); Western blotting of extracts from transformed plants to show they produced the pr17 protein (example 3); and demonstrating that the transgenic plants are resistant to *Phytophthora infestans* (examples 4 and 6), drought (example 5), and salt (example 7).

The instant specification fails to provide guidance for isolation or synthesis of nucleic acids encoding other derivatives of pr17 or other proteins with "an intrinsic affinity to plasmodesmata" and fails to provide guidance for using those nucleic acids to produce plants that are tolerant of drought, fungal infection, salt and temperature. The instant specification also fails to provide guidance for a method of using any nucleic acid to produce plants that are tolerant of temperature extremes. The specification also fails to provide guidance for plants other than potato that are tolerant of drought, fungal infection, salt and temperature.

Tacke et al (1996, Nature Biotechnol. 14:1597-1601) teach that potato plants transformed with a nucleic acid encoding wild-type pr17 or pr-17 with an N-terminal extension other than SEQ ID NO:1 were not resistant to potato virus X (pg 1596, paragraph spanning the columns).

Given the limited teachings in the specification showing production of disease resistance in potato with a single nucleic acid and the failure of the instant specification to teach isolation of nucleic acids encoding proteins with "an intrinsic affinity to plasmodesmata" other than pr17 + SEQ ID NO:1, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those that also confer tolerance to drought, fungal infection, salt and temperature.

A multitude of proteins would have "an intrinsic affinity to plasmodesmata", including any protein involved in the partition of assimilates like membrane transport proteins and proteins

involved in plasmodesmata structure. Thus, undue trial and error experimentation would be required to screen the multitude of nucleic acids encoding these proteins, to identify those that confer tolerance to drought, fungal infection, salt and temperature to plants, if such plants could even be obtained.

Additionally, not all plants are susceptible to infection by *Phytophthora infestans*, so it is unclear how transformation with any protein could increase the tolerance of a plant to infection by *Phytophthora infestans* or how such an increase could be measured in such plants.

Given the specificity of protein-protein interaction and given that potato leaf roll virus does not infect all plants, it is unclear that a nucleic acid encoding pr17 + SEQ ID NO:1 would work in other plants, particularly distantly related ones like cereals.

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

8. Claim10-15 and 17-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method of using a multitude of DNA molecules that encode a protein with "an intrinsic affinity to plasmodesmata." In contrast, the specification only describes a coding sequence from potato leaf roll virus that encodes pr17 with an N-terminal extension of SEQ ID NO:1. Applicant does not describe other DNA molecules encompassed by

the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Because the sequences are not described, the method of using the sequences to produce plants that are tolerant of drought, fungal infection, salt and temperature is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 10-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 10 is indefinite in its recitation of "transfecting" in line 5 and claim 11 is is indefinite in its recitation of "transfected" in line 2. Transfection is a process in which a nucleic acid is tarsfreed to a plant via a virus, which replicates in the cell. Transfection is not a process used to transfer nucleic acids to plants; the process used is transformation.

Claim 10 is indefinite in its recitation of "intrinsic affinity to plasmodesmata". The nature of that affinity and the manner in which it is intrinsic is unclear.

The term "increased" in claims 10, 18 and 23-27 is a relative term that renders the claims indefinite. The term "increased" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The change in salt concentration or tolerance should be compared to a known standard.

The term "extreme" in claim 10 is a relative term that renders the claim indefinite. The term "extreme" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What temperature is considered extreme is unclear.

The multiple use of "or" in claim 10 is awkward; it is suggested that the first two uses in line 2 be replaced with a comma.

Claims 10-27 are indefinite because they lack agreement between the preamble of the methods and the positive method steps. Methods must be circular; the final step must generate the item the method is intended to produce. For example, the method in claim 10 of producing plants or parts thereof that have increased tolerance to drought, fungal infection salt and temperature ends in transfecting a plant, tissue or cell with a nucleic acid, when it should end in the production of plants or parts thereof that have increased tolerance to drought, fungal infection salt and temperature.

Claim 11 lacks antecedent basis for the limitation "the transfected plant cell".

Claim 12 lacks antecedent basis for the limitation "the plant regenerated in (b)".

Claim 14 is indefinite in its recitation of "p17" as the protein is --pr17--.

Claim 14 is indefinite in its recitation of "derivative thereof". The extent to which and manner in which the derivative varies from pr17 is unclear.

Claim 16 is missing the word --sequence-- after "amino acid", as SEQ ID NO:1 contains more than one amino acid.

Claims 17 and 19-22 are awkward. The source of the plant cells and tissues should be clearly separated from the recitation of the plants themselves, *i.e.*, "wherein the plants are ... and wherein the plant tissues or plant cells are ...." Additionally, "from" should either be present before each kind of plant or only before the first, but not the mixture currently in the claims. The latter style is easiest to read. Lastly, "derived from" is unclear - does it mean the plant cells and tissues have been altered in some way from those in the plants themselves or is it intended to mean that the plant cells and tissues where isolated form the listed plant kinds.

Claims 18 and 23-27 lack antecedent basis for the limitation "the increase in tolerance of plants".

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 10-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Tacke et al (1996, Nature Biotechnol. 14:1597-1601).

Tacke et al teach a method of producing potato plants transformed with a nucleic acid encoding the potato leaf roll virus movement protein pr17 with and without a hydrophilic N-terminal extension of SEQ ID NO:1; this method involves transforming calli and regenerating them into plants (pg 1597, right column, and pg 1600, left column, paragraph 2). The transformed plants were also vegetatively propagated (pg 1596, left column, paragraph 2), making plants from the transformed plants. This method would inherently be one of increasing tolerance of drought, fungal infection, salt and temperature, as the method steps are identical to the instantly claimed method.

13. Claims 10-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Herbers et al (1997, Plant J. 12:1045-1056) taken with the evidence of Tacke et al (*supra*).

Herbers et al teach a method of producing tobacco plants transformed with a nucleic acid encoding the potato leaf roll virus movement protein MP17 with the N-terminal extension taught

by Tacke et al (pg 1046, right column, paragraphs 2-3, and pg 1054, left column, paragraph 2). MP17 is another name for pr17. Because these plants are notably shorter than control plants (Fig. 1), they would have increased tolerance to drought (due to lower surface area). Because the method of producing these plants involves the same steps as the instantly claimed methods, Herbers et al inherently teach a method of producing plants with increased tolerance of drought, fungal infection, salt and temperature.

14. Claims 10-14, 17-19, 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lucas (WO 97/06669).

Lucas teaches a method of producing tobacco plants by transformation with the movement protein of tobacco mosaic virus (pg 11-15). Because these plants have increased dark respiration under high temperatures (pg 34 and table 9), they are heat tolerant. Because these plants are notably shorter than control plants (pg 37-38), they would have increased tolerance to drought (due to lower surface area). The movement protein of tobacco mosaic virus interacts with plasmodesmata to effect virus transport (pg 2, lines 29-31), and would thus have an intrinsic affinity to plasmodesmata. It would also be a "derivative of" p17. Because the method of producing these plants involves the same steps as the instantly claimed methods, Lucas inherently teaches a method of producing plants with increased tolerance of fungi, including *Phytophthora infestans*.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Sonya Williams, at (703) 305-2272.

Anne R. Kubelik, Ph.D.
September 3, 2002

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600